

Remarks

Claims 1-11, 13, 27 and 28 are pending. Claims 14-26 and 28 were withdrawn. Claims 1-11, 13, and 27 are rejected.

Claims 1, 3, 5 and 6 are currently amended. Support for the amendment is found at least in the claims pending prior to entry of the current amendment. No new matter is introduced.

Applicants are re-submitting herewith, the terminal disclaimers previously filed on October 3, 2007 to comply with the recently updated and accepted Power of Attorney filed November 13, 2009.

Rejections under 35 U.S.C. § 103(a)

Claims 1-11 and 13 are rejected as being allegedly obvious over U.S. patent application publication No. 2002/0094440 by Llanos (“Llanos”) in view of U.S. patent application publication No. 2004/0170685 by Carpenter et al. (“Carpenter”). Applicants respectfully traverse these rejections.

To establish a *prima facie* case of obviousness of a claim drawn to a combination of elements, the PTO must provide evidence and well-grounded technical reasoning establishing that (1) every claim element is present in the prior art and (2) the claimed combination is a **predictable outcome** of the teachings of prior art (see, KSR v. Teleflex, 550 U.S. 398 (2007)). Applicants respectfully point out that the Examiner fails to establish a *prima facie* case of obviousness.

Claim 1 and claims depending therefrom of the instant application define a medical article. The medical article comprises a coating disposed on at least a portion of an implantable medical device. The coating includes (a) a fluorinated polymer; and (b) a biologically beneficial polymer. The biologically beneficial polymer is selected from hyaluronic acid, phosphoryl

choline, poly(ethylene oxide-co-propylene oxide), polyaspirin, and poly(ester amide) polymers, and the biologically beneficial polymer is conjugated to a biologically active agent. The fluorinated polymer is selected from: (i) products of polymerization of fluorinated olefins; (ii) fluorine-containing cyclic polymers having a main chain with an asymmetrical cyclic structure selected from a group of polymers of repeating units of cyclically polymerized perfluorally vinyl ether, perfluorobutenyl vinyl ether, and a combination thereof; and (iii) copolymers of perfluoro-2,2-dimethyl-1,3-dioxole with perfluoroolefins or with perfluoro(alkyl vinyl) ethers.

Note, all of category (i), (ii) and (iii) fluorinated polymers are biodurable polymers and are not degradable.

Llanos describes a copolymer formed of two moieties, the first moiety is either a vinylidene fluoride (VDF) or tetrafluoroethylene (TFE), and the second moiety is capable of copolymerize with the first moiety and imparts toughness or elasticity to the copolymer (paragraph [0010]). Llanos further provides that the second moiety can be hexafluoropropylene (HFP), TFE, VDF, 1-hydropentafluoropropylene, perfluoro(methyl vinyl ether), chlorotrifluoroethylene (CTFE), pentafluoropropene, trifluoroethylene, hexafluoroacetone and hexafluoroisobutylene (paragraph [0020]). Therefore, as a person of ordinary skill in the art would recognize, **Llanos teaches a fluoro copolymer which is (1) hydrophobic and (2) non-degradable.**

Carpenter discloses bioactive agents coated with biodegradable, bioactive polymers. Bioactive agent is produced *in situ* by degradation of the polymer (see paragraph [0022]). **In such a coating, biodegradability of a polymer forming the coating is a necessary property**

of the polymer. Indeed, to impart bioabsorbability properties to the coating, Carpenter suggest using a poly(ester amide) for forming the coating. As such, Carpenter teaches away from using a biodurable polymer for forming a coating as is in Llanos. Carpenter therefore is not combinable with Llanos. For the same reason, Carpenter teaches away from the claims of instant application, which require polymers which are biodurable.

In sum, Llanos and Carpenter cannot make claims 1-11 and 13 *prima facie* under 35 U.S.C. 103(a). Applicants respectfully request the Examiner to withdraw the rejections of these claims over Llanos in view of Carpenter.

Claims 1-11 and 13 are rejected as being allegedly obvious over U.S. patent No. 6,703,040 to Katsarava et al. (“Katsarava”) in view of Llanos and Carpenter.

The claims of instant application, Llanos, and Carpenter are discussed above.

Katsarava describes a poly(ester amide) and teaches that such a poly(ester amide) polymer can be used to form a bioerodable coating on a supporting structure (col. 5, lines 1-3). Note, similar to Carpenter, Katsarava teaches away from combining a poly(ester amide) polymer with a fluoro polymer in Llanos. As such, Katsarava and Llanos are not combinable. Further, Katsarava teaches away from the claims of instant application, which require polymers which are biodurable.

Since both Katsarava and Carpenter are not combinable with Llanos and teach away from claims 1-11 and 13 of the instant application, Katsarava in view of Llanos and Carpenter cannot make these claims *prima facie* obvious under 35 U.S.C. §103(a). Applicants respectfully request

the Examiner to withdraw the rejections of claims 1-11 and 13 over Katsarava in view of Llanos and Carpenter.

Claim 27 is rejected as allegedly being obvious over Llanos in view of Carpenter and further in view of U.S. patent No. 6,451,337 to Smith et al. (“Smith”).

Claim 27 depends from claim 13, which, in turn, depends from claim 1. Claim 27 therefore require all limitations of claim 1, discussed above. Llanos and Carpenter are discussed above.

Smith discloses a polymeric conjugate of diazenium diolates. As the Examiner notes, Smith aims to develop a low cost, readily biodegradable, biocompatible nitric oxide donor polymer composition. Since Llanos teaches using biodurable/biostable polymer to make a coating, Smith is not combinable with Llanos. Further, Smith teaches away from the claims of instant application, which require polymers which are biodurable. Therefore, Llanos in view of Carpenter further in view of Smith cannot make claim 27 *prima facie* obvious under 35 U.S.C. §103(a). Applicants respectfully request the Examiner to withdraw the rejection of claim 27 over Llanos in view of Carpenter further in view of Smith.

Conclusion

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. **07-1850**. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 07-1850. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. **07-1850**.

Respectfully submitted,

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